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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET-NO.	CONFIRMATION NO.
10/018,806	05/07/2002	Peter Szego	027841.0101-JSC	2125

26853 7590 07/15/2003

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[REDACTED] EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
1654	[REDACTED]

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/018,806	SZEGO, PETER
Examiner	Art Unit	
Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 May 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5,8-10 and 13-24 is/are rejected.
- 7) Claim(s) 6,7,11 and 12 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____ .
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4,6</u> . | 6) <input type="checkbox"/> Other: _____ . |

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1. The abstract of the disclosure is objected to because of the presence of the legal phraseology “said” in the third-to-last line. Correction is required. See MPEP § 608.01(b).
2. Claims 3-5, 8-10, and 13-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 3, 5, 8-10, 16, 17, 20, and 21 are indefinite because they are incomplete. Although the claims refer to a general formula (I/a), the general formula is not recited in these claims or in any claims upon which they depend. See MPEP 2173.05(s). Claim 4 is indefinite because it is not clear if the scope of the claim is to be limited to the preferred ratio or not. It is suggested that the “preferably...” phrase could be deleted from the claim and made the subject matter of a further dependent claim. Claim 16 is indefinite because it is not clear if the scope of the claim is to be limited to the exemplified wanted activity or not. It is suggested that the “e.g.,...” phrase could be deleted and made the subject matter of a further dependent claim.
3. Claims 1-24 are objected to because of the following informalities: At claim 1, line 5, “synthesized” is misspelled. In claim 1, the same variable k is used both to designate covalent bonds and to designate the upper limit to the value of the variable m. The claims need to be re-written so that the same variable is not assigned different meanings and does not designate different aspects of the invention. Appropriate correction is required.
4. Claims 11-15 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer to other claims in the alternative only. Note that claim 11 is dependent upon both claim 1 and claim 6, and that claims 12-15 are each dependent upon at least two different claims. See MPEP § 608.01(n), especially section (I)(B)(3). Note that depending

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upon how the dependencies of these claims are resolved, the claims may have to be amended to that they are complete, i.e. so that the various general formulas referred to in these claims are explicitly recited in them or in claims upon which they depend. See the above rejection under 35 U.S.C. 112, second paragraph.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-5, 16, and 22-24 are rejected under 35 U.S.C. 102(a) as being anticipated by the Ho et al article (Food Chemistry, Vol. 68, pages 449-455). The Ho et al article teaches ϵ -poly-L-lysine with a degree of polymerization of 25-30 covalently conjugated to dextran. The conjugate has improved emulsifying activity and antibacterial activity. See, e.g., the abstract; page 449, column 1; and page 450, column 1, second paragraph; and Table 1. With respect to claims 22-24, an intended use limitation does not impart patentability to compound claims where the compound is otherwise anticipated by the prior art.

7. Claims 1-5, 16-19, and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by the Noshio et al article (Chemistry Express, Vol. 7, pages 753-756) in view of the Shima et al article (Agric. Biol. Chem., Vol. 41, pages 1807-1809). The Noshio et al article teaches ϵ -poly-L-lysine covalently conjugated to caprylic, lauric, or stearic acid. About 50% or about 100% of the amino sidechains are acylated. The conjugates have greater antimicrobial activity than the unconjugated components. See, e.g., page 753, last paragraph, through page 754, first full

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paragraph; page 754, fourth full paragraph; and tables 1 and 2. The Shima et al article, cited in footnote 1 of the Noshio et al article, shows that the ϵ -poly-L-lysine has a degree of polymerization of about 25-30 (see page 1808, paragraph bridging columns 1 and 2, and Figure 3). With respect to instant claim 18, the fatty acid groups which are conjugated to the ϵ -poly-L-lysine will increase the hydrophobicity of the conjugate, and thus will inherently increase the ability of the conjugates to cross cell membranes. Sufficient evidence of similarity is deemed to be present between the conjugates of the Noshio et al article and the instant claimed conjugates to shift the burden to Applicants to provide evidence that the claimed conjugates are unobviously different than those of the Noshio et al article. With respect to claims 22-24, an intended use limitation does not impart patentability to compound claims where the compound is otherwise anticipated by the prior art.

8. Claims 1-4, 8, 16-19, and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Lobberding et al (U.S. Patent No. 5,849,893). Lobberding et al teach peptide nucleic acids having ϵ -polylysine, δ -polyornithine, or poly-2,4-diaminobutyric acid backbones with nucleic bases attached to the alpha amino groups through $\text{CH}_2\text{-C(O)}$ spacers. The degree of polymerization ranges from 1 to 30. The peptide nucleic acids are used as medicaments or as diagnostic aids. See, e.g., the Abstract; column 2, formula (I) and line 64; column 10, lines 22-63; and claim 1. With respect to claims 22-24, an intended use limitation does not impart patentability to compound claims where the compound is otherwise anticipated by the prior art.

9. Claims 1-4, 16-19, and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by the Shima et al article (J. Poly. Sci., Pol. Lett. Ed., Vol. 23, pages 245-249). The Shima et al article teaches epsilon-poly-L-lysine with a degree of polymerization of 25-30 to which is bound

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.Cu²⁺ in aqueous solution. See, e.g., page 245, third paragraph, and page 245, lines 2-3. Copper is a paramagnetic metal. Sufficient evidence of similarity is deemed to be present between the conjugates of the Shima et al article and the instant claimed conjugates to shift the burden to Applicants to provide evidence that the claimed conjugates are unobviously different than those of the Shima et al article. With respect to claims 21-24, an intended use limitation does not impart patentability to compound claims where the compound is otherwise anticipated by the prior art.

10. The examiner interprets general formula (I) in claim 1 as not requiring that both an [(i)Mx] group and a [(k)Mx] group be present in each bioconjugate, because otherwise it would not have been necessary to introduce the terminology [(k/i)Mx] as is done in the last two lines of claim 1. If the examiner's interpretation is incorrect, Applicants are required to inform him of their interpretation of the claim language in the response to this Office action.

11. Claims 9, 10, 13-15, and 20 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, and the claim objections set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Claims 6, 7, 11, and 12 would be allowable if rewritten to overcome the claim objections set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. The prior art of record does not teach or suggest conjugates having the structures recited in these claims.

The Inaki et al article (Nucleosides & Nucleotides, Vol. 17, pages 339-350) and the Kricheldorf et al article are cited as art of interest, but are not deemed to teach or suggest the instant claimed invention. The Inaki et al article teaches a degree of polymerization n=8, which

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. does not suggest Applicants' claimed range for the variable r. The Kricheldorf et al article is silent as to its degree of polymerization.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
July 11, 2003